Part 2- Session Papers for the EPA 23rd Annual National Conference on Managing Environmental Quality Systems

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Information Technology / Policy Impacts and How to Proactively Manage the Quality of Information Products

The Top Ten Data Issues Facing the Typical Organization (Thomas Redman, Navesink Consulting Group)

Future Shock – Current and Future Impacts of Information Technology and Information Policy on Management Systems for the Quality of Public and Private Information Products (Jeff Worthington, U.S. EPA)

Retooling the Management System for Quality: How Managers and Quality Mangers May Sharpen Tools and Skills to Effectively Manage Product Quality for Information (Jeff Worthington, U.S. EPA)

Environmental Measurements

Volatile Water Samples at 4 Degrees Celsius: Environmental Folklore or Fact? (Rameen Moezzi, Tetra Tech EM, Inc.)

Ensuring the Quality of Privatized Proficiency Testing Studies (Curtis Wood, Environmental Resource Associates)

Development of Field Analytical Methods for Long-Term Monitoring of Military Important Chemicals (David Splichal, U.S. Army)

Managing Information as a Product

Tools of Quality – An Interactive Session on Identifying Features and Innovative Measurement (Jeff Worthington, U.S. EPA)

10 Laws of Managing Information as a Product (Jeff Worthington, U.S. EPA)

EPA's Research and Science Challenge (Robert Shepanek, U.S. EPA)

Intergovernmental Efforts to Unify Environmental Data Quality Policy

Guidance and Tools for Implementing Environmental Quality Systems (Mike Carter, U.S. EPA)

The EDQW: An Integrator of Environmental Quality throughout DoD (Jackie Sample, U.S. EPA)

The Approach of the Uniform Federal Policy on Environmental Quality to Quality Assurance Project Plan (Robert Runyon, U.S. EPA)

Workshop: OEI Update on Quality Improvements

Modeling Value of Information to Set Priorities for Quality Needs (Art Koines, U.S. EPA)

Using the State-EPA Exchange Network to Improve Data Quality and Timeliness (Pat Garvey, U.S. EPA)

Data Standards: Improving Communication Capabilities for Sampling and Analysis Data (Mike Carter and Linda Spencer, U.S. EPA)

Intergovernmental Efforts to Unify Environmental Data Quality Policy (continued form morning)

Quality Assurance/Quality Control for Ordnance and Explosives Investigations and Cleanup (Laura Wrench, Versar, Inc.)

Understanding Analytical Data Quality for Project Managers (Fred McClean, U.S. Navy)

The Top Ten Data Issues Facing the Typical Organization

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Abstract: *The typical organization is faced with a range of issues that prevent it from taking full advantage of its data resources. Among these issues are poor connection between strategy and data, low accuracy levels, inadequate knowledge of what data resources are available, and lack of management accountability. While one might hope that the Internet and stunning advances in database and communications technologies might ease these issues, just the opposite is happening. The issues are becoming more complex, not more tractable. Further, the expected growth in the sheer quantity of data exacerbate these issues.*

Key Words: Data, Data Inventory, Data Resources, Data Quality, Data Management, Organization

Future Shock - Current and Future Impacts of Information Technology and Information Policy on Management Systems for the Quality of Public and Private Information Products

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ABSTRACT

New technology development often drives both public and private business processes by providing improvements such as better products, increased customer satisfaction, and increased productivity. Growth in information technology is rapidly changing how many forms of information are developed, formatted, and shared via electronic means such as the Internet. Information is gaining increasing value as a product in this new work environment. Customer expectation's continue to change; this includes the Public's expectation regarding the quality of government information and data. This presentation describes important features of the changing technology such as the "network effect" and profiles changing expectations.

Retooling the Management System for Quality: How Managers and Quality Managers May Sharpen Tools and Skills to Effectively Manage Product Quality for Information

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ABSTRACT

Rapid change requires that managers and quality mangers better prepare to adapt their management systems to change. Managers needs to identify the changes and the impacts of the changes. Managers need to re-confirm their own management systems and recognize the gaps between the processes that are already managed and the new process that need to be controlled and managed. Managers need to have a plan to not only re-configure their management systems, but also to ensure that the management system remains flexible enough to accommodate future changes.

This presentation describes some basic "how to" processes for managers to consider when incorporating changes into their management systems including new training, improved identification of processes which require control, and a basic plan to monitor and track product quality.

Volatiles Water Samples at 4°C: Environmental Folklore or Fact?

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"*Cool to 4°C" is the preservation requirement specified by EPA's SW-846 manual for groundwater samples collected for volatile organic compound analysis. SW-846 also states that samples that will not be analyzed within seven days may also be acidified to a pH of 2 or less. Despite care in packing and shipping, samples may occasionally arrive at an off-site laboratory at temperatures exceeding 4°C. EPA guidance under the CLP program does not require qualification of the data associated with elevated temperatures under routine circumstances, provided that the samples are acidified and analyzed within seven days after collection. If it is unlikely that data quality is affected by elevated temperatures, then resampling is not warranted.*

I Introduction

Groundwater samples collected for volatile organic compound (VOC) analysis are stored in a cooler immediately after sampling. At the end of the day the samples are typically delivered to a nearby off-site laboratory or packed with ice in a camp-style ice chest for overnight shipment to a more distant laboratory. Upon arrival at the laboratory, the sample temperatures are recorded; the target temperature is 4°C. This temperature is taken from Volume II of the standard handbook for environmental analyses, Environmental Protection Agency's (EPA) SW-846 manual (EPA 1986). The manual notes without much further explanation that the requirement for VOC sample preservation is "Cool to 4°C" and that VOC samples that will not be analyzed within seven days may also be acidified to a pH less than 2.

The samples may occasionally arrive at the laboratory at temperatures exceeding 4°C, due to shipping delays, handling practices, and hot weather as well as to the inexact science of packing sample coolers. Environmental professionals and clients may question the effect temperatures above 4°C may have on the data quality, particularly in the case of VOC samples, and may call for resampling. Resampling, however, may involve considerable effort and expense, and should be justified by reasonable concerns that data quality has been affected by the elevated temperature.

The simple presentation of the SW-846 guideline has led over the years to some discussion in the environmental field as to how literally "Cool to 4°C" is to be taken; whether there are quality control limits that can be observed without affecting data quality; and in what cases corrective action should be taken. The original EPA guidance has been expanded in practice by ±2°C because of concerns expressed over the difficulty of maintaining samples at exactly 4°C during transport. Some samplers have also proposed that EPA consider that samples arriving at the laboratory with ice left in the coolers have met the preservation requirements.

II Other Occurrences of 4°C

The SW-846 guideline conveys a sense of confidence not only because it is ubiquitously referred to in environmental work, but also because it specifies an exact temperature. The guideline, however, could equivalently be stated as "Refrigerate," because home refrigerators are commonly set at 4°C (40°F). This temperature slows the growth of bacteria and keeps them from multiplying—and the fewer bacteria there are, the less likely a person is to get sick.

4°C is also a temperature well-known to physical scientists and limnologists because it is at this temperature that water attains its maximum density. This is easily observed in lakes, where in summer the cooler water is on the bottom of the lake, but in winter, as water temperatures reach 4°C and less, the colder, less dense water remains on top and may form ice.

III Sampled vs In-situ Groundwater

Groundwater from industrial sites in the San Francisco Bay Area is typically at a temperature of approximately 15°C (59°F) when sampled; this is about 5°C cooler than room temperature (20°C/68°F) and about 10°C warmer than the recommended preservation guidelines. Why might VOCs be especially vulnerable after sampling, in the few days to two weeks before analysis, when they may have been in the environment for years or even decades?

Suspicions may be raised because sampled groundwater differs in several ways from in-situ groundwater. During sampling, groundwater journeys into a well, then typically is drawn up through tubing and poured into a tall, cylindrical clear glass vial. The vial has little surface area at the top, and is sealed with a Teflon-coated septum cap.

The sample container system is not a completely closed one, as anyone who has tried storing VOC vials in a semivolatile extract refrigerator and found methylene chloride upon VOC analysis can attest. Trip blanks are another reminder that VOCs can enter the container. An ingress/egress route may be either through the septum (the route noted in SW-846) or between the glass rim and the Teflon liner. However, the two processes—from ambient air to water in a closed container, and vice versa—are not physically symmetrical.

Most natural groundwater has a pH in the range of 5 to 8. VOC samples are often collected in vials containing hydrochloric acid, which acidifies the water to a pH of 2 or less. Liquids with a pH of 2 are commonly encountered in daily life, as for example, Coca-Cola.

It is interesting to note that unopened VOC sample vials may spend some pre-analysis minutes to hours at the lab unrefrigerated, during the sample log-in process, on the lab bench, and on an autosampler.

IV Degradation

A decline in the data quality of VOC samples could be due to two factors: 1) a transformation process, and 2) a loss from the container. The intent of the "Cool to 4°C" specification, while also providing as little energy to the system as possible for any transformation processes, may be mainly the same as for food in a refrigerator: to protect samples from bacterial degradation. There are many different kinds of bacteria, and they are found in a wide range of conditions, from the Arctic to hot springs, and even in acidic environments. They draw on a wide source of materials for food. But generally speaking, most bacteria like (a) neutral pH, (b) moderate temperatures, and (c) human food.

Many of the persistent chemicals of concern encountered in the environmental field are persistent because they are highly resistant to bacterial degradation. On the VOC target compound list, the aromatic compounds (benzene, toluene, etc.) are among the most susceptible to attack by bacteria.

The acidification of VOC water samples presumably kills most of the bacteria present in the samples. In fact, pH reduction alone appears to be the primary factor involved in preserving the samples from degradation or dehydrohalogenation (Maskarenic 1990).

V Volatilization

In the case of VOC samples, people calling for resampling due to elevated temperatures are often more concerned with possible losses due to volatilization rather than degradation, especially because samples are usually acidified. A factor compounding the concern over temperature and volatilization may be that these are familiar concepts (like days and holding times) to laypersons, while more obscure parameters, such as internal and surrogate standards, which may also reflect on the data, are not. People also know that molecules are very small. Thus they may be envisioning that the VOC molecules, some of which (vinyl chloride, for example) are considered gases, quickly begin to make their way to the top of the vial as temperatures go up, and then squeeze out.

It is also known from daily life, however, that molecules can be kept in containers. Helium, for example, can stay in balloons (especially Mylar balloons) for days. And bottled water purchased at room temperature in plastic containers and capped with hand-tight plastic tops often contains trihalomethanes, which are on the regular VOC target compound list.

Evaporation of the water itself from the vial would have an effect on VOC results. The factors influencing the amount of gases and VOCs present in groundwater can be complicated. However, if there is any data suggesting that elevated (>4-25°C) temperatures occurring between normal collection and analysis times actually cause a discernible volatilization of standard list VOCs from a routine, acidified water sample, it is not widely publicized.

VI EPA Contract Laboratory Program

EPA provides additional guidance on sample preservation in its Contract Laboratory Program (CLP), which is an analytical program designed for Superfund sites that is less well-known than SW-846. CLP has two components: an analytical Statement of Work (SOW) (EPA 1999a), and the National Functional Guidelines for Organic Data Review (EPA 1999b). The SOW specifies that samples should be preserved to a pH of 2 or below at the time of sample collection, and that "all samples must be iced or refrigerated at 4°C (±2°C) from the time of sample collection until analysis."[1] The CLP SOW further states that EPA notification is required only when cooler temperatures exceed 10°C upon arrival at the laboratory, at which juncture the EPA Region involved will provide instructions on whether or not to proceed with sample analysis.

The passages below are from the Functional Guidelines' "Holding Times" section, which is the only place in the review guidelines where sample temperatures are mentioned. The "Criteria" section of "Holding Times" states that:

> *Water samples that have not been maintained at 4°C (±2°C) and preserved to a pH of 2 or below should be analyzed within seven days from sample collection. If insufficient ice is used to ship samples, the laboratory may receive samples with no ice left in the cooler. Under these circumstances, the temperature of the samples may exceed 4°C.*

Note that the possibility of "no ice left in the cooler" is mentioned; however, the data review guidelines do not require any qualification of the data for even this extreme case. The next reference to temperature transgressions is in the "Evaluation" section:

If there is no indication in the SDG narrative or the sample records that there was a problem with the samples (e.g., samples not maintained @ 4°C or containing headspace in the samples), then the integrity of samples can be assumed to be good. If it is indicated that there were problems with the samples, then the integrity of the sample may have been compromised and professional judgment should be used to evaluate the effect of the problem on the sample results.

The "Action" section follows:

> *If technical holding times are exceeded, document in the data review narrative that holding times were exceeded and qualify the sample results as follows (also see Table 1):*
>
> *a. If there is no evidence that the samples were properly preserved and the technical holding times exceeded 7 days, qualify positive results for aromatic compounds with "J" and sample quantitation limits with "UJ." Use professional judgment to determine if and how non-aromatic volatile compounds should also be qualified.*

b. If the samples were properly preserved but the technical holding times exceeded 14 days, qualify positive results with "J" and sample quantitation limits with "UJ."

Table 1. Qualification of Volatile Analytes Based on Technical Holding Times

MATRIX	***PRESERVED***	***> 7 DAYS***	***> 14 DAYS***
Water	*No*	*All Aromatics**	*All Compounds*
	Yes	*None*	*All Compounds*
Non-Aqueous	*No/Yes*	*Professional Judgment*	*Professional Judgment*

** Reviewer should use professional judgment to determine if data for additional compounds require qualification.*

As shown above, the data review guidelines leave qualification for elevated cooler temperatures up to professional judgment, but do provide basic suggestions for qualification of the data based on preservative and holding time. Whether "properly preserved" refers to both temperature and acid, or only acid, is debatable. However, the guidelines do not assume that samples subjected to elevated temperatures have been resampled, and do not specify qualification—either estimation or rejection—for elevated temperatures. They also do not specify any qualification for water samples that have been analyzed *within* seven days from sample collection. After seven days, qualification is focused primarily on aromatic compounds, which indicates that volatilization is not the main concern. After fourteen days, qualification for all VOC target compounds is suggested equally for both preserved and nonpreserved samples.

Due to the professional judgment clause, validators do not treat volatiles data associated with elevated cooler temperatures consistently. Studies and data are hard to find, making it difficult to definitely support professional judgment. Neither SW-846 nor CLP guidance documents require an action (such as qualification or resampling) to take for elevated temperatures. Some validators qualify the data with the statement, "I don't know whether or not the data might be affected." They may also assume that they are required to qualify the data because 4°C is perceived as a QC limit. Other validators believe that because they do not have evidence to suggest that the data is affected, there is no reason to qualify the data. Many people find it easier to resample or estimate the data rather than defend the data against well-intentioned but nebulous suspicions.

VII Conclusion

The main purpose of acidifying VOC water samples is presumably to inhibit degradation by killing bacteria. The intent of maintaining the samples at 4°C between collection and analysis is probably also to inhibit chemical or microbial degradation. However, the pH reduction appears to be the primary factor in preservation. Some people assume that elevated cooler temperatures are likely to cause volatilization and thus affect data quality. But there is no evidence that volatilization is not adequately prevented during sample transport by the septum-cap of the vial,

or that 4°C provides any more protection than the acid alone during this time. Another reason that not much degradation of VOCs would be expected to occur during periods of elevated cooler temperatures is because the time involved (typically hours to a day) is so short.

Despite care in packing and shipping, short-term exceedances of the industry standard "Cool to 4°C" preservation guideline may occasionally occur upon transport of VOC water samples to an off-site laboratory. EPA SW-846 and CLP documents note that this could be a potential problem, but do not make any recommendations as to resampling, or even qualifying, the data. Because the 4°C preservation has not been rigorously tested, the data review guidelines of EPA's CLP program leave data qualification up to the professional judgment of data users and reviewers. They do not themselves recommend any qualification of data from VOC water samples that have been acidified and analyzed within seven days after collection.

There has been little indication thus far that elevated temperatures (>4-25°C) occurring between normal collection and analysis times affects the data quality for acidified, properly collected VOC groundwater samples. Thus it would appear that at this time there is little justification for a professional judgment that, under routine circumstances, data should be qualified as estimated (J) or rejected (R). If data quality is not affected, then resampling is certainly not warranted.

The best use of the "Cool to 4°C" guidance may be to have people treat groundwater samples collected for VOC analysis well, pack coolers with plenty of ice, ship them promptly, and put them into a refrigerator when they arrive at the laboratory, rather than subject the temperatures of transport coolers to exacting scrutiny. There have been few studies on the effects of refrigeration on VOC water samples, perhaps because there has been little indication thus far that this affects the data over short periods of time. More studies would be a welcome addition to the maturing environmental field.

[1] *Note that this could be interpreted as "refrigerated at 4°C (±2°C) or iced."*

[This paper does not necessarily reflect EPA policy.]

VIII References

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Ensuring the Quality of Privatized Proficiency Testing Studies

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In 1999, US EPA ended its almost three-decade long administration of proficiency testing studies for environmental labs when the program was privatized. Today there are some 15 private companies and state entities that conduct environmental PT studies for laboratories in the US.

Non-participation or failure in mandatory PT studies can have significant negative impacts on a laboratory. Poor PT performance can result in costly corrective actions, additional time and expense for re-testing, loss of customers and potentially a loss of accreditation; essentially, a lab's license to do business. Aside from the costs to a lab, poor PT performance can negatively affect the environmental monitoring and remediation industries due to loss of laboratory capacity and by raising questions about previously submitted data.

With the significant importance placed on proficiency testing, it is imperative that the level of challenge is consistent from provider to provider and that all labs are evaluated fairly and consistently, no matter which provider they choose or are required to use. Understanding this, the authors of the three main guidance documents for PT providers included ample criteria for conducting technically sound and consistent PT studies. Four years after privatization, the implementation of these "requirements" is questionable and, with no centralized oversight, labs and states are forced to take a "buyer beware" attitude when selecting and approving PT providers.

This paper will present the requirements for conducting effective PT studies and the issues surrounding their implementation. This information will allow laboratories, accrediting authorities and data end-users to practice the necessary due diligence when dealing with proficiency testing studies and PT providers.

When reviewing a final report from a proficiency testing (PT) study, laboratories usually look first for the "Not Acceptable" evaluations. Inevitably, labs are concerned that each Not Acceptable truly reflects their performance and are not the result of PT provider errors. While Accrediting Authorities (AAs) have these same concerns, they also require assurance that the PT studies have effectively and compliantly assessed laboratory performance. As the AAs rely on PT results to help make critical accreditation decisions, it is essential that they are able to ensure the defensibility of the laboratory performance evaluations.

There are many important aspects to conducting effective, fair and compliant proficiency testing. An essential part of ensuring the efficacy of a PT study is that providers verify the assigned value, homogeneity and stability of every analyte in every sample in every study. Good science, as well as NIST Handbook 150-19 and the NELAC standards require providers to properly characterize their PT samples.

The NIST NVLAP PT provider accreditation program addresses only part of the WS and WP and none of the RCRA-Solids samples and analytes. Another important limitation of the NIST program is that it

includes virtually no ongoing oversight to ensure that providers are properly analyzing their PT samples. Therefore, ensuring the defensibility of the providers' performance evaluations is left to the individual laboratories and AAs. Increasingly, both are requesting data packages that support the validity, compliance and defensibility of PT studies. With this documentation in hand and an understanding of the PT provider requirements, labs and states can gain a sense of security that is not supported by the current PT provider accreditation process.

A discussion follows of some of the critical analytical and data review steps that are an essential part of high-quality compliant proficiency testing studies. The applicable requirements are located in NIST Handbook 150-19, *Chemical Calibration Providers of Proficiency Testing*, Section 285.33(h)(6) and the *2003 National Environmental Laboratory Accreditation Conference Constitution, Bylaws, and Standards*, Chapter 2 Appendix B for the applicable requirements. The proposed 2004 INELA Draft Interim Standard *Accreditation of Environmental Laboratories and Related Organizations* has added a relevant Appendix I to the Standard.

Analytical Methods

Both NIST NVLAP and NELAC requirements include criteria to ensure that the analytical methods used by providers are sensitive and precise enough to detect heterogeneity or instability in their PT samples. Both sets of criteria are the same for water pollution analytes while the NIST NVLAP criteria are tighter for water supply analytes. Only the NELAC Standard addresses RCRA-Solid analytes. Both Standards require the provider to conduct a method validation study to determine the repeatability of each of their analytical procedures and then to ensure that the repeatability of each meets defined criteria for every analyte.

Assigned Value Verification

Prior to opening any proficiency testing study, PT providers must analyze each of their PT samples to ensure that the assigned value of each analyte has been properly set. The acceptance limits for this testing are calculated as a defined percentage of the acceptance limits that the participant laboratories must meet. In all cases, these are tighter than the limits for the participant labs. For example, the PT provider acceptance limits for all EPA/NIST NVLAP WS and WP analytes are one-third the corresponding participant laboratory acceptance limits. Additionally, the NELAC Standard requires that the standard deviation of the assigned value verification testing be less than one standard deviation calculated from the USEPA or NELAC regression equations or fixed percentage limits, which are used to establish the laboratory acceptance limits. To meet the assigned value verification criteria, the provider must take a statistically valid, randomly selected subset of samples that have been packaged for distribution and analyze these by previously validated analytical methods. The provider is required to verify the samples as they are presented to the laboratories. Therefore, the samples provided as concentrates are analyzed as such and the whole volume and soil samples must be verified on the final packaged material.

The mean and standard deviation for each analyte must be compared with the applicable NIST NVLAP and/or NELAC criteria. As laboratories are evaluated on their performance for each analyte, it is critical that providers verify the assigned value of every analyte. Failure of one analyte from a multi-analyte standard should result in the invalidation and re-manufacture of that batch of standards.

Homogeneity Testing

As stated in NELAC Chapter 2, Section B.3, "PT sample homogeneity is essential to ensuring that all laboratories are treated fairly." To this end, both NVLAP and NELAC require that PT providers prove

that each batch of PT samples is homogeneous at a 95% confidence interval. The January 2004 INELA Draft Interim Standard provides a specific procedure in Chapter 2, Appendix I. This procedure requires providers to test at least 5 samples from each PT sample batch. These data points are then used to determine the homogeneity of each analyte in the sample. This testing must be done on each batch, prior to the study open, for each analyte in each sample.

Stability Assessment

Once a PT study has closed, both NVLAP and NELAC require that PT providers reanalyze each sample lot to verify that the concentration of every analyte remained constant during the study. This testing can only be initiated after the study has closed and must be completed prior to the issuance of final study reports. NELAC allows a window of 21 days from the close of a study to the issuance of reports to conduct this testing.

Analytes found to have not been stable during the course of a study cause the study to be invalidated for the problem analyte(s). The provider is obligated to conduct no charge retesting for all affected laboratories.

Study Statistics Review

After the close of each study, the data for each analyte from all participant laboratories must be carefully reviewed to ensure the validity of the study. The study mean for each analyte should be reviewed in relation to the internally verified assigned value and the historically predicted mean. The relationship of the study mean to the assigned value (recovery) and standard deviation of participant results for each analyte are critical to verifying that every lot of PT samples is "fit for use". Historically tracking both recovery and standard deviation of results provides an invaluable indicator of any issues that might affect the quality and defensibility of the study. In addition, it is critical to compare the study failure rate to the provider and USEPA historical failure rates for each analyte. Unfortunately, there is no oversight body to review the pass/fail rates of the different providers to assess whether all provide a reasonably comparable challenge.

With the initiation of laboratory accreditation by method/technology, it is critical to evaluate the PT results for each analyte to determine if there are any method biases that may be causing laboratories that are using selected methods to fail their PTs. It is essential that these reviews be conducted by professionals that are experienced in the use of the methodologies referenced by the participant laboratories.

Study Discussions

Communicating to laboratories and AAs about any anomalous or abnormal issues found during the data review is another obligation of the PT provider. Both the EPA/NIST and NELAC Standards require that PT providers supply a summary of the study statistics along with a study anomaly discussion report. This report is included with all final evaluation reports sent to laboratories and states. By making all participant labs and AAs aware of any unusual aspects of the study, the provider is aiding them in making appropriate Corrective Action and accreditation decisions.

Lack of Oversight

As presented above, ample technical requirements exist to ensure that privatized proficiency testing studies result in accurate, compliant, consistent and fair evaluations of America's environmental laboratories. Unfortunately though, there is not and has never been an oversight mechanism in place to ensure that any of these requirements are being met on a consistent basis. Therefore, laboratories and states that wish to practice due diligence must understand the requirements and determine the compliance and quality of the providers' PT studies themselves.

Development of Field Analytical Methods for Long Term Monitoring of Military Important Chemicals

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Long term monitoring (LTM) of groundwater on contaminated and remediated sites is an essential and expensive activity for environmental stewardship and regulatory compliance. Approximately 50-70% of the total costs associated with LTM are associated with sampling and analysis at fixed laboratories. Field analysis would eliminate sample transport and expensive laboratory analysis, which could reduce LTM costs significantly. However, many field methods produce screening rather than definitive data and cannot be used to satisfy regulatory requirements. Also, appropriate methods are not available for several analytes that are important to the Department of Defense. The Engineer Research and Development Center (ERDC) of the US Army Corps of Engineers is currently engaged in a program to develop field analytical processes and technologies for more effective environmental monitoring which will be acceptable to the regulatory community, as well as meet the stewardship and fiscal needs of the Army.

Long term monitoring (LTM) of groundwater on contaminated and remediated sites requires collection, transport, and analysis of chemical samples over a number of years. Sampling at a specified frequency and subsequent analysis at an off-site laboratory can contribute as much as 50-70% of the total costs associated with LTM. Field analysis could reduce LTM costs significantly by eliminating sample transport and expensive fixed laboratory analysis, but many field methods only produce screening data that will not meet regulatory requirements. Also, some field methods are expensive to implement and perform due to factors such as necessities for instrument operation, need for highly trained analysts, and non-rugged nature of the instrumentation. In addition, current field technologies are not adequate for detection of some analytes that are important to the military. The Engineer Research and Development Center (ERDC) of the US Army Corps of Engineers is currently engaged in a program to develop field analytical processes and technologies for more effective environmental monitoring which will be acceptable to the regulatory community, as well as meet the stewardship and fiscal needs of the Army. The LTM program seeks to develop technologies that will meet requirements that include quick analytical turnaround time (< 4 hrs), defensible data generation, 25-50% cost savings compared to traditional laboratory analysis, detection of military important chemicals at levels of concern, portability, remote operation, *in situ* operation, and acceptability to Federal, State, and local regulatory agencies. The program goals are being addressed in three major work areas: 1) Development and implementation of new protocols for acquiring definitive data inside and outside the analytical laboratory; 2) Further development and

deployment of currently available commercial and governmental technologies (COTS/GOTS); 3) Development and deployment of new and emerging technologies for a real-time *in situ* monitoring system (RTISMS) for detection of volatile organics and military unique compounds.

Several projects to achieve the program requirements started during this fiscal year. Research is being conducted to develop new quality assurance and quality control protocols for field and laboratory analytical methods. Commercially available technologies are being modified and optimized to better support Army LTM needs. Applicability of direct push wells is being evaluated for long term use with groundwater-compatible sensors. Several emerging technologies, including miniaturized mass spectrometers, solventless extraction techniques, biosensors and lab-on-a-chip devices are also undergoing laboratory. A progress summary will be presented.

Many field analytical methods for identification of volatiles [EPA 2003; Ho *et al.* 2001], pesticides, poly-aromatic hydrocarbons (PAH), and explosives [FRTR web site] are available commercially, and could reduce LTM costs significantly, but many field methods produce screening rather than definitive data. The methods – frequently inexpensive kits (See for example, Strategic Diagnostics, Inc., Newark, DE) - are often class-based rather than analyte specific or operate at high detection limits (ppm) that are above regulatory action levels. These method characteristics can be useful for gathering initial site information that will be used for designing more rigorous studies but do not meet regulatory requirements for full characterization of an area of concern. The Triad approach to environmental project management [ITRC 2003] strongly advocates use of real time analytical measurement with quality controls and data validation for site characterizations. Demonstration of sustained remediation requires detection limits at or below action levels and implementation of a quality assurance program. Highly sensitive technologies must be combined with appropriate quality control parameters under a quality assurance system as described in SW-846 Test Methods for Evaluating Solid Wastes [EPA 2000]. The goal of quality assurance programs in fixed analytical laboratories is to ensure that data generation will occur under well-defined and controlled conditions. Training, implementation of standard operating procedures, use of traceable calibration standards, calibration verification, demonstration of contaminant-free analysis (method blanks) as well as appropriate recovery and quantitation of analytes of interest (blank spikes), and batch documentation are all used to create the necessary atmosphere for generation of definitive data. Depending on the technology, these procedures can be translated to the field, though most likely at initially increased cost compared to costs for current deployments of field analytical technologies. An integral part of our development and deployment of technologies for LTM is the incorporation of necessary and appropriate quality controls so that field data will be generated with the same level of confidence that accompanies fixed laboratory data.

As we work towards deployment of field technologies that will include sufficient quality controls, the LTM research team is recommending changes to current LTM practices to reduce costs associated with laboratory analysis without sacrificing data quality. For example, samples from sites with a known and limited number of contaminants are frequently analyzed for a full suite of target analytes. Laboratory costs for method performance and data reporting could be greatly reduced by constraining the analysis to only the known contaminants during some or all of the monitoring events. Other typical practices which are often not included in the base price

of sample analysis such as analysis of matrix spikes and reporting of tentatively identified compounds could be eliminated or purchased less frequently without significant negative impact on data quality. These and other proposed changes to typical laboratory practices, to be published as an ERDC Technical report in FY04, will be evaluated through statistical examination of historical laboratory data acquired for several monitoring projects by the Environmental Chemistry Branch, the Corps of Engineers quality assurance environmental analytical laboratory. Information obtained from the evaluation will be used to train and develop a neural network as a tool for LTM project managers to reduce quality control costs.

Commercial off-the-shelf technologies (COTs) also present opportunities for reduction of LTM costs. A review of COTs for environmental monitoring by the LTM research team will be published in FY04 as an ERDC Technical Report. Several resources for information about commercial field analytical technologies are available [EPA 2003; FATE web site; ETV web site; FRTR web site]. The LTM research team is evaluating a number of technologies such as direct push (DP) wells, passive diffusion bags (Columbia Analytical Services, Rochester, NY) and HydraSleeve samplers (EON Products, Inc. Snellville, GA) [Parker and Clark 2002], and the Twister™ Desorption and Automation System (GERSTEL, Baltimore, MD) [David *et al.* 2003] that could be deployed relatively quickly for Department of Defense monitoring purposes. Installation of direct push wells is significantly less expensive than installation of hollow stem auger drilled wells, and comparative studies have shown excellent agreement between analytical results for samples from the two types of wells [Kram *et al.* 2001]. Research investigating well hydraulics with discrete interval-type samplers, corrosivity and leaching from wells over time, and performance with military unique chemicals is underway. Evaluation of sensor use in DP wells is planned. We are also developing *in situ* extraction devices for analyte extraction in the field to be coupled with field analysis by a portable gas chromatograph. Preliminary results for *in situ* extraction/concentration of explosives by a solid phase extraction filter connected to a submerged pump showed greater than 70% recovery for all analytes tested with the exceptions of tetryl and HMX. Measured recoveries decreased by approximately 40% when analytes were eluted 36 hours after the water extraction.

The greatest opportunity for creation of a real time *in situ* monitoring system lies with development and deployment of emerging technologies that can be interfaced with off-the-shelf products such as data processing software and communications software and hardware. New detection systems are likely to require up-front capital costs that exceed single sampling event expenses, but are also likely to begin to provide cost savings within 3 to 5 years [EPA 2003]. Instrumentation that can be used for sample analysis for multiple wells will begin cost savings sooner. We are involved with developmental research in three promising areas: miniature mass spectrometry [Henry 2002; Badman and Cooks, 2002], catalytic DNA microfluidic sensors [Li and Lu 2000], and antibody-based biosensors [Baeumner 2003].

Several portable mass spectrometers are available commercially (for example, instruments produced by Tri-Corders Environmental Inc., McLean, VA; Griffin Analytical Technologies, Inc., West Lafayette, IN; Bruker Daltonics, Inc., Billerica, MA; INFICON, East Syracuse, NY), but most are intended for gas detection, had less sensitivity than required for the RTISMS, or were not an appropriate size for deployment into a very confined space such as a monitoring well. Instruments such as the CBMS Block III (Bruker Daltonics, Billerica, MA) are

currently used by the military for detection of chemical and biological agents in air. Pre-commercial technologies such as the miniature time-of -flight mass spectrometer (MALDI-TOF) [Laiko *et al.* 2000] that shows promise for high molecular weight analytes and the Syagen Technology system that interfaces a gas chromatograph to a quadrupole ion trap with a photoionization source coupled to a time of flight mass spectrometer (GC/QitTOF) are documented in the scientific literature. Another instrument, the miniature cylindrical ion trap developed by Graham Cooks and co-workers at Purdue University [Riter *et al.* 2002] shows potential for meeting the LTM program needs. The instrument is highly sensitive, small, lightweight, and capable of detecting target analytes in water. We are embarking on a research partnership with the Cooks team to build a similar mass spectrometer which will be capable of high sensitivity for RDX, TNT, HMX, and other contaminants of concern for the Army, perform sample analysis in less than 4 hours, be capable of remote*, in situ* operation and data transfer. The instrument will use a single-sided hydrophobic membrane sample inlet [Riter *et al.* 2001], have capability for electron impact ionization as well as negative ion chemical ionization, and be able to perform tandem mass spectrometry for selective detection of targets in complex matrices [Busch *et al.* 1988]. The miniature mass spectrometer will undergo laboratory and field evaluation as part of the research effort.

Lab-on-a-chip technologies are also excellent candidates for *in situ* monitoring due to their low power needs, small physical size, small sample volume requirements, and ease of interface with different detection technologies. The LTM research team is collaborating with Yu Li and co-workers at the University of Illinois at Champaign-Urbana to enhance a sensor that uses catalytic DNA to selectively detect target analytes such as lead ions at low concentrations [Li and Lu 2000]. The catalytic DNA is immobilized in the pores of a molecular gate membrane on a microchip to form nano-scale reaction vessels. The DNA is single-stranded and is designed through combinatorial *in vitro* selection to have high specificity for a selected analyte. The strand forms a molecular pocket around the analyte and then releases a fluorescent tag. A fluorescence detector is used for quantitation. Modifications to the sensor, combinatorial *in vitro* synthesis, and amplification of analyte-specific DNA sequences are underway to enable detection of depleted uranium and explosives such as RDX and TNT.

The LTM research team is also investigating use of antibody-based biosensors for detection of military unique chemicals. Commercial systems such as the FAST 6000, developed by Research International (Monroe, WA) in collaboration with the US Naval Research Laboratory, and the Luminex® xMAP™ Technology, available from Bio-Rad Life Sciences (Hercules, CA), use immobilized antibodies and fluorescent detection for rapid, accurate, and sensitive identification and quantitation of explosives and other small molecules in groundwater. The LTM program researchers are pursuing development of antibodies to perchlorate and HMX for immobilization onto surfaces such as magnetic microbeads. Detection could be accomplished by release of fluorescent tags, as with the xMAP™ Technology and the FAST 6000. Alternative detection scenarios, such as surface acoustic wave [Barie and Rapp 2000] or microcantilever [Moulin et al. 2000], could facilitate use of such sensors inside direct push wells. Laboratory and field-testing of the antibody-based biosensor will be performed.

The LTM program is addressing three key areas in development and deployment of field analytical technologies: quality assurance, commercially available technologies, and emerging

technologies. Each area has potential to create significant cost savings for the Army's environmental stewardship and compliance requirements. The program design will provide interim improvements over approximately 8 years. Initial cost savings will come through changes to quality assurance/quality control in the fixed analytical laboratory. Evaluation of commercial technologies for Army use is likely to yield several approaches to cost savings within 2-5 years. Cost benefits from development of emerging technologies into Real Time *in situ* Monitoring Systems are not expected to start immediately upon deployment in 5-7 years due to capitol investments. However, reduction in expenses for sampling, transportation, and fixed laboratory analysis should exceed capitol costs within approximately 3 years. The LTM program anticipates 25-50% reduction on analytical costs, faster turnaround time for results, and expanded capability for detection of military unique compounds due to use of appropriate field analytical technologies.

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Tools of quality: An Interactive session on Identifying Features and Innovative Measurement

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Identifying the features (or characteristics) of information as a product is a first step towards planning, measuring, and reporting the quality of that information. Measurements are a vital tool for managers and quality managers because the measures provide a means to quantify success levels as well as definitively report on improvements. This presentation and interactive session is intended for managers and information managers and will set the stage for reliance on planning and measurement processes in managing information as a product. Audience participation is encouraged and there will be an open discussion of features of information as a product that are valued by the audience.

10 Laws of Managing Information as a Product

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Information is often considered a resource as well as a product by commercial and public enterprises. Managers and quality managers routinely treat information technology (IT) and information management (IM) as separate activities in an organization; however, information processes are essential to effective (and competitive) development of an organization's product. Treating information processes (i.e., production and distribution) in terms of their contribution to information itself as a product will assist management in establishing priorities. This technical presentation summarizes information processes in the form of 10 laws. Managers and quality managers can benefit from this simple listing of 10 basic laws because the laws provide a focus for discussion and development of management systems which focus on information. A summary of the 10 laws follows:

LAW 1: You must have information about your information in order to manage your information as a product.

LAW 2: You must have a common language in order to discuss the management of information as a product.

LAW 3: You must understand the nature of information in order to manage information as a product.

LAW 4: You must identify the specific information and information processes that are of interest to you in order for you to manage information as a product.

LAW 5: You must identify what you value about information in order to manage information as a product.

LAW 6: You must be able to measure what you value about information in order to manage information as a product.

LAW 7: You must be prepared to set expectations about your measures in order to manage information as a product.

LAW 8: Your strategy for managing information must be in alignment with the strategy for the enterprise in order to manage information as product.

LAW 9: You get the information you plan for.

LAW 10: You must provide current reports to senior management of the quality of information and implementation of the system for managing quality so that managers can manage the quality.

All of the books in the world contain no more information than is broadcast as video in a single large American city in a single year. Not all bits have equal value. *Carl Sagan*

KEY WORDS
information, information product, information quality, 10 laws, quality assurance, quality managment, quality planning

EPA's Research & Science Challenge

Robert Shepanek, U.S. EPA

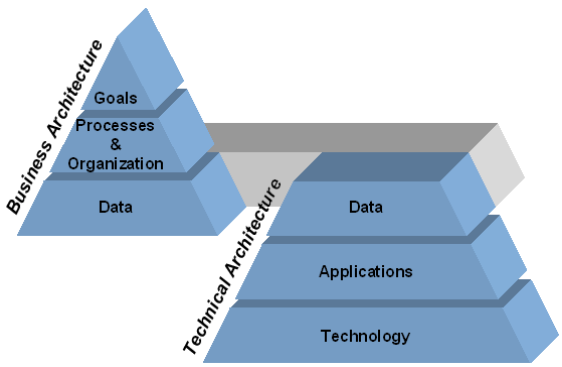
The business of research and science at the U.S. Environmental Protection Agency (EPA) continues to evolve in meeting the challenge of protecting human health and the environment. This evolution is characterized by a constant increase in office-specific, cross-office, and cross-agency objectives that must be met to address the Agency's mission priorities. The challenge to meeting these objectives lies not only in accessing this vast amount of valuable data, but also in sharing this data among inter- and intra-agency partners. Those expanding arenas of responsibility are further compounded by an emphasis on e-government priorities, including increased emphasis on collaboration with partners outside the Agency.

Striving to meet this challenge, the EPA research and science community is busy optimizing existing resources, incorporating new technologies, improving collaboration within and outside the Agency, leveraging internal research and development, and pursuing other efforts to strengthen research and science at the Agency. However, many teams, data, technology, and other resources are still untapped or otherwise underutilized outside of the groups in which they reside. Consequently, the full potential of research and science at the EPA will only be realized through a coordinated focus and commitment across the Agency from senior leadership to bench scientists. The Research and Science Architecture (RSA) is a living tool that describes the anticipated results of that coordinated strategy.

The Research & Science Architecture

Using business processes and technological resources, EPA's research and science community is working to develop the RSA, a component of the EA that focuses on addressing the issues, satisfying the needs, and enhancing the operations of EPA's research and science community. This community crosses many organizational boundaries within the agency and is comprised of members from most Program Offices, Regions, Centers, and Laboratories as well as EPA Partners and other collaborators involved in Environmental Science and Research.

The RSA presents the strategic vision for research and science at the Agency and describes the resulting flow of business processes required to carry out that strategy, the data needed to conduct those processes, the tools and information systems that have the greatest potential to enable processes and best manage that data, and finally, the core technologies that will best support those tools and systems.



Why Enterprise Architecture?

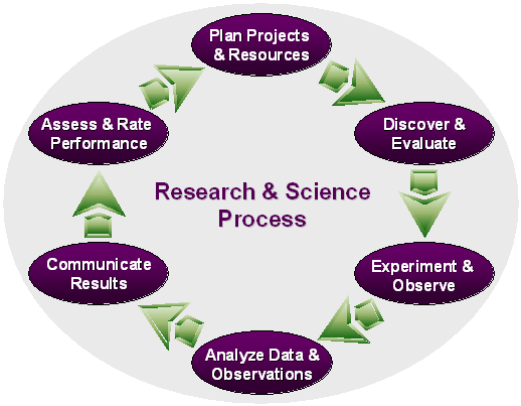
- EA is a unified plan for investment in the future of EPA's research and science and will make it easier to develop successful business cases for investment decision making.
- EA is an ongoing method used to define the processes, data, tools, and other technology that best support an enterprise's mission.
- EA facilitates coordination between different enterprise components (e.g., offices) to leverage common processes and resources and thereby more effectively and efficiently support the enterprise's mission.
- The RSA focuses the stated strategic objectives of EPA's research and science leaders into a plan that will layout the path to the desired target or future state.

Key RSA Objectives

The RSA lays out the coordination, tools and technology necessary to support and enable EPA's evolving research & science business by accomplishing the RSA's stated mission to:

> *Effectively support and enable research and science at the EPA with modern processes and technologies that subsequently improve the integrity, accessibility, integration, and reuse of reliable scientific information based on science priorities and sound science practices.*

The RSA's key research and science objectives for accomplishing this mission are as follows.



- Implement effective, efficient, and secure collaboration with trusted partners both within and outside the EPA and at all Agency levels as required to meet the Agency's research and science goals.
- Manage scientific information to provide the right information to the right people at the right time in the right format.
- Provide the appropriate scientific computing services and infrastructure on-demand.
- Manage geospatial capital and support the EPA Geospatial Blueprint initiative to maximize accessibility, quality, and reuse and to minimize duplication.
- Leverage past investments in an effective and efficient manner via a catalog of reusable EPA research & science technologies.

These objectives not only reflect the desired future state of the Agency's business, but also present a new view of supporting and enabling technologies that members of EPA's research and science community can expect on their desktops and workstations in the post-implementation time frame. This "desktop view" may include a number of new tools, portals, and applications contributing to the realization of the RSA's objectives. [Should we move this to the front?]

Realizing the RSA

The RSA blueprint and implementation plans for enhancing EPA research and science are currently being developed and will be included in the EPA's September 2004 EA submission to OMB.

If you would like to be involved in this process, please contact Megan Quinn at Quinn.Megan@EPA.gov or (202) 564-6729.

For more information, see the EPA Enterprise Architecture and ORD CIO intranet web sites, and stay tuned for the RSA blueprint and implementation plans as well as other future RSA development

The New ANSI/ASQ E4-2004 Standard: What's New and Changed

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I. BACKGROUND:

The quality system policy supporting the U.S. Environmental Protection Agency has been based on the 1994 version American National Standard ANSI/ASQ E4 for the past decade. The E4 standard was the first quality management standard developed explicitly to address the needs of environmental programs for conformity assessment and was derived from several standards in use in the late 1980s and early 1990s, including ISO 9001 and ASME NQA-1. The E4 standard provided for quality assurance and quality control practices appropriate for environmental data collection and use and for application to the design, construction, and operation of engineering technology in environmental programs. Besides providing the basis for the EPA Quality System, the E4 standard has been adopted for use by other Federal and State organizations and by the private sector as well.

As an ANSI standard, E4 was required to undergo periodic review to determine its continued effectiveness for conformity assessment. The ASQ Energy and Environmental Division (EED) completed a revision of the standard under the auspices of the ANSI Z1 Accredited Standards Committee on Quality, Environment, Dependability, and Statistics. The review and revision process was completed in February 2004 when the revised E4 was approved by ANSI as *Quality Systems for Environmental and Technology Programs - Requirements with Guidance for Use* (ANSI/ASQ E4-2004).

II. RESULTS OF THE REVISION:

The review of the 1994 version and feedback from its users indicate that only relatively minor revisions were needed, mostly for added clarification. Most of the changes were largely cosmetic. Feedback from users pointed to some confusion in separating requirements from guidance. Some users had difficulty in determining what should be auditable specifications. The E4 Work Group, which comprised representatives from the U.S. EPA, other Federal departments and agencies, State agencies, academia, and private companies, concluded that re-formatting the standard would be appropriate and used ISO 9001:2000 as the model for the new format. At the same time, it was decided to retain the three-part configuration of the standard as well as the "planning, implementation, and assessment" approach used previously.

The publication of ISO 9001:2000, *Quality Management Systems - Requirements*, in December 2000 provided an opportunity to align E4 for increased compatibility with ISO 9001. The revised E4 was organized in the format of an ISO standard. The requirements or specifications were retained in the main body of the standard and are auditable. The non-mandatory guidance was moved to an annex and clearly labeled as discretionary. In addition, a crosswalk between E4 and ISO 9001:2000 was included to show the increased compatibility. As a result, it is clear that E4 addresses all of the elements in ISO 9001:2000 and perhaps more importantly, does so from an environmental perspective. This has led to E4 having been recognized as an equivalent quality management system (QMS) standard to ISO 9001:2000 for environmental programs. Thus, ANSI/ASQ E4 joins other standards like AS 9000 for aerospace, QS 9000 for automotive, and TL 9000 for electronics and communications, as a sector-specific (i.e., environmental) QMS standard.

In addition, the publication of a new terminology set in ISO 9000:2000, *Quality Management Systems - Fundamentals and Vocabulary*, enabled the Work Group to update the E4 terms and definitions for added compatibility and consistency.

There were valuable lessons learned from the 1994 version's implementation that were included in the revision. These resulted in:

- more explicit definitions on roles responsibilities for managers and quality professionals;
- more explicit statements on quality assurance manager reporting and organizational location (i.e., organizational independence);
- incorporation of due process considerations; and
- explicit reliance on the principle of *graded approach*.

1. **STRUCTURE OF ANSI/ASQ E4-2000:**

The structure of the American National Standard ANSI/ASQ E4-2004 is as follows:

Foreword

0 Introduction

1 Scope

2 General Principles and Applications

3 Normative References

4 Terms and Definitions

5 Management Systems

6 Collection and Evaluation of Environmental Data

7 Design, Construction and Operation of Environmental Technology

Annex A Terms and Definitions (Normative)

Annex B Guidance on the Use of ANSI/ASQ E4 (Informative)

Annex C Crosswalk between ANSI/ASQ E4 and ISO 9001 (Informative)

IV. NEXT STEPS:

The publication of ANSI/ASQ E4-2004 is expected this spring by ASQ and its impact on environmental programs should be immediate and smooth inasmuch as few substantive changes have been made. It is anticipated that EPA policy (i.e., EPA Orders 5360.1 A2 and 5360 A1) will be revised to reflect the new E4 standard. At this time, the timetable for completing the policy changes cannot be estimated.

It is also anticipated that the ASQ/EED will offer new training on the re-authorized E4 by the fall of 2004.

Guidance and Tools for Implementing Environmental Quality Systems

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Clem Rastatter, Versar, Inc.
Nicole Weymouth, Versar, Inc.

There are many efforts underway throughout EPA to help ensure data of the appropriate quality are collected and used. EPA's Information Quality Guidelines have given this topic renewed concern. The Uniform Federal Policy for Implementing Environmental Quality (UFP-QS) has been formally adopted by EPA, DoD, and DOE for hazardous waste programs. The OSWER Quality Management Plan has been revised to reflect this policy. There are various electronic tools available for use in planning and verifying environmental data quality (such as VSP, SEDD, FORMS II Lite). In addition, the Environmental Data Standards Council (EDSC) is working on a comprehensive environmental data standard which will help utilize these tools and allow data to be shared, analyzed, and archived effectively.

The EDQW: An Integrator of Environmental Quality Throughout DoD

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Doug Scarborough, U.S. Army, Army Environmental Center
William Batschelet, U.S. Air Force AFCEE
Carla Schultz

The EDQW has initiated major efforts to improve environmental data quality throughout DoD, both by participating as a member of the IDQTF and through development of DoD-wide products. The DoD Quality Systems Manual for Environmental Laboratories (QSM) is now on Version 2 and contains a series of technical appendices designed to provide implementation direction to DoD laboratories. A DoD-wide Quality Instruction, an Assessment Protocol based on the QSM, and a set of procurement policies and model contract language are close to completion.

The Approach of the Uniform Federal Policy on Environmental Quality to Quality Assurance Project Plans

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Mike Carter, U.S. EPA, Federal Facilities Restoration and Reuse Office
Clem Rastatter, Versar, Inc.
Nicole Weymouth, Versar, Inc.

The IDQTF has also developed the Uniform Federal Policy for Quality Assurance Project Plans (UFP-QAPP) – a framework for writing QAPPs. The UFP-QAPP includes a new paradigm in data review, as well as a set of minimum QA/QC activities that are required for data collection under Superfund. It is designed to ensure a consistent approach to writing QAPPs and reduce the time and difficulties in reviewing QAPPs. It emphasizes the use of a "graded" approach and the Systematic Planning Process, and provides optional fill in the blank worksheets.

Modeling Value of Information to Set Priorities for Quality Needs
Setting Priorities for Improving Information Quality: A Case Study Applying Value of Information Analysis to a Typical Environmental Risk Assessment and Management Decision

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In this presentation, we demonstrate a systematic approach for calculating the optimal amount of information about uncertain factors in a typical environmental risk assessment and management decision. By using a formal definition of information quality, we are able to place a value of information on different possible efforts to improve the quality of information supporting the environmental decision. The case study is based on EPA's cancer risk assessment guidelines. Monte Carlo analysis is used to characterize the nature and extent of uncertainty for inputs into the case study decision.

The situation described in the case study – i.e., the decision, local conditions, and quality of available information -- is one typically faced by State and local government officials. However, EPA provides some of the general information used in the decision and sometimes funds State and local efforts to gather other more locally specific information. The case study results should be of individual interest to EPA and its State and local implementation partners. They also hint at some potential advantages from collaboration based upon a common view of information priorities.

The case study analysis illustrates the need for greater attention to principles advanced by EPA's Quality Community, i.e.:

- Information quality needs are best understood with a well-defined information use or decision in mind.
- Better information quality reduces uncertainty.
- Some sources of uncertainty are more important than others.
- The quality of a decision is best understood in light of the probability and consequence of a "bad" decision.
- The value – and priority -- of an information quality improvement should reflect its ability to reduce uncertainty that may contribute to a "bad" decision.

The case study shows how value of information analysis can be useful in a specific regulatory decision. It further implies that the value of information can be a powerful guiding principle in

setting more general priorities for information collection, management and analysis. The challenge is to find a practical and sensible way to apply the principle more generally to guide the choice of information program priorities.

Using the State-EPA Exchange Network to Improve Data Quality and Timeliness

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ABSTRACT

The National Environmental Information Exchange Network (the Network) has been established byEPA,the States, and Indian Tribes with three primary objectives in mind:

- *improve public and employee access to information;*
- *reduce burden and costs; and*
- *improve the quality and timeliness of environmental data.*

The Network is focusing on using the Internet and open standards to accomplish these objectives.

In this session, attendees will gain an understanding of the rationale for and history of the Network, hear about its operating status, and learn about the specific steps being taken to improve data quality.

KEYWORDS

exchange network, quality improvement, information access, burden reduction

Data Standards - Improving Communication Capabilities for Sampling and Analysis Data

Mike Carter and Linda Spencer, U.S. EPA

Abstract:

This presentation will highlight a suite of draft data standards designed to improve the consistency in the electronic reporting of sampling information and analytical results: Environmental Sampling, Analysis, and Results Data Standard, Sampling Treatment Data Standard, Method Data Standard, Measure Data Standard, Attached Binary Object Data Standard, Date and Time Data Standard. The standards are a product of the Environmental Data Standards Council (a partnership of EPA, States, and North American Tribal organizations). Other data standards promulgated by the Council will be discussed and the standards development process will be reviewed.

Quality Assurance/Quality Control for Ordnance and Explosives Investigations and Cleanup

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Abstract: *While the methods used to investigate and cleanup sites containing ordnance and explosives (OE) often differ significantly from "traditional" HTRW methods, defensible decision-making at these sites requires the same assessments of the quality of data. EPA has developed an example QAPP to demonstrate how data quality can be specified and assessed during the investigation of an OE site. The example is based on the IDQTF's UFP-QAPP.*

Understanding Analytical Data Quality for Project Managers

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Abstract: *The focus of this presentation is understanding the intersection of project-specific requirements and planning for analytical data quality. It is designed to assist the non-chemist project manager in understanding the parts of the Systematic Planning Process that should drive analytical requirements, and selecting an analytical laboratory and the appropriate methods to meet project requirements. It highlights guidance from the UFP-QAPP and DoD QSM.*